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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/035,832

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David W. Morris

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10/07/2008

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EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

10/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/035,832	Applicant(s) MORRIS ET AL.	
	Examiner ANNE L. HOLLERAN	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,30,32,33,35,43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20, 30, 32, 33, 35, 43 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 6/23/2008 is acknowledged.

Claims 20, 30, 32, 33, 35, 43 and 44 are pending and examined on the merits.

Claim Rejections Withdrawn:

The rejection of claims 20, 30, 32, 33, 39, 40-42 and 45-48 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods where the expression product that is detected is an mRNA having a sequence of SEQ ID NO: 1587, does not reasonably provide enablement for methods where the expression product that is detected is an mRNA having a sequence at least 98% identical to SEQ ID NO: 1587, where the mRNA encodes a polypeptide with protein phosphatase activity; or an expression product is one that forms a duplex with a polynucleotide that hybridizes under highly stringent conditions to a nucleotide sequence comprising SEQ ID NO: 1587 is withdrawn in view of the amendment to the claims.

The rejection of claims 43 and 44 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn upon further consideration.

The rejection of claims 30, 35, 39, 42-46 and 48 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claims 35, 39-42, and 45-47 under 35 U.S.C. 102(e) as being anticipated by Bertucci (US 2003/0143539 A1; published Jul. 31, 2003; effective filing date is Dec. 7, 2001) is withdrawn in view of the amendment to the claims.

Claim Rejections Maintained:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20, 30, 32, 33, and 35 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of diagnosis of colon cancer comprising the differential detection of PPP3CC *protein* [emphasis added] levels, does not reasonably provide enablement for methods for diagnosing colon cancer, lymphoma, stomach cancer, prostate cancer, breast cancer or carcinoma, comprising either the differential detection of PPP3CC mRNA levels, where the PPP3CC mRNA is defined as a nucleotide sequence of SEQ ID NO: 1587. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The basis for this rejection is that the teachings of the specification do not enable the intended use of the claimed methods for the diagnosis of colon cancer, lymphoma, prostate cancer, or stomach cancer because the specification fails to provide evidence of differential expression of the nucleotide sequence of SEQ ID NO: 1587.

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Applicants' arguments have been carefully considered, but fail to persuade. Applicants state that the previous Office action states that the specification is enabling for methods of detecting mRNA having the sequence of SEQ ID NO: 1587. However, upon review, it is noted that the following qualifier was placed in the Office action "Even if the prior rejection under 112, first paragraph is overcome, the following will be applied", where the following was a rejection that discussed use of a genus of mRNAs (having at least 98% sequence identity with SEQ ID NO: 1587) in comparison to a subgenus, an mRNA comprising the sequence of SEQ ID NO: 1587. Therefore, the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 43 and 44 remain rejected under 35 U.S.C. 102(b) as being anticipated by McGarrity (McGarrity, T.J. et al., Gut, 32: 1121-1126, 1991) as evidenced by Billingsley (Billingsley, M.L. et al., Proc. Natl. Acad. Sci., USA, 82: 7585-7589, 1985).

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Applicants' arguments have been carefully considered, but fail to persuade. McGarrity teaches a method of detecting a protein that is identified as either calcineurin, calmodulin kinase II or a novel calmodulin binding protein (see page 1125, left column). In addition, the Office has provided evidence that this protein likely was calcineurin (Billingsley), and that the molecular weight given by McGarrity appears to be a mischaracterization. Therefore, the rejection is maintained for the reasons of record.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
October 1, 2008
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643